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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,599	10/03/2000	Leigh T Canham	124-796	1219
23117 7590 09/10/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER AZPURU, CARLOS A	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 09/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/647,599	Applicant(s) CANHAM ET AL.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 180-189 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 180-186, 188 and 189 is/are rejected.
- 7) ☒ Claim(s) 187 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the request for continued examination filed
08/15/2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 180-189 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With regard to claim 180, there is no support for the language referring to the "corrodible" characteristic of the claimed implants. It is therefore suggested that the language of the specification at page 4, lines 14-17 instead be used.

Claims 181-183 have no support for the claimed porosity ranges and values.

Regarding claim 184, there is no support for the range set out. Applicant is requested to use the language of page 7, lines 20-23.

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With regard to the range of claim 185, the original specification does not include a value equal to 2mm in this range as seen at page 5, line 18.

Claim 186 refers to "atomic percent" which is not clearly defined or recognized in the art. Since this may be due to a translation issue, applicant is requested to clarify the percent amount.

Claim 188 does not have support in the original specification in that phosphorus is not disclosed.

These claims are rejected for containing new matter and written description.

Claim 189 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for platinum, does not reasonably provide enablement for all anti-cancer substances. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's invention is not inclusive of all anticancer drugs in that only certain elements such as metals, which can be incorporated into the porous silicone implant

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are contemplated. No disclosure or suggestion is made of other anticancer bioactives such as taxol. Correction is requested.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 186 recites the limitation "the element" in claim 180. There is insufficient antecedent basis for this limitation in the claim.

Claim 180 does not refer to an "element". Correction is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 180 – 184 are rejected under 35 U.S.C. 102(b) as being anticipated by WO'97/06101 (WO'101).

WO'101 discloses a silicone particle which exist in microporous, mesoporous and macroporous form. Resorption (corrodible characteristic) although not taught is an inherent characteristic of the material selected. In this case, the same mesoporous silicon particles with the same porosity are selected, so that this characteristic may be considered a new characteristic of a known material. Porosity is disclosed as between 4 and 70% at page 3, line 13. The amount of drug distributed through the implant, the depth of impregnated bioactive, as well as the amount of resorption are dependent upon the material and its porosity. Similarly, the duration of drug delivery is also determined by the claimed material. Since the reference discloses the same porous silicone material with the claimed parameters, the instant claim is anticipated by WO'101.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 180-184 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO'101.

WO'101 discloses a silicone particle which exist in microporous, mesoporous and macroporous form. Resorption (corrodible characteristic) although not taught is an inherent characteristic of the material selected. In this case, the same mesoporous silicon particles with the same porosity are selected, so that this characteristic may be considered a new characteristic of a known material. The amount of drug distributed through the implant, the depth of impregnated bioactive, as well as the amount of resorption are dependent upon the material and its porosity. . Similarly, the duration of drug delivery is also determined by the claimed material. Since the reference discloses the same porous silicone material with the claimed parameters the claimed silicone particle Would have been within the skill of the ordinary practitioner given the disclosure of WO'101. Further the ordinary practitioner would have expected similar therapeutic results from using the porous silicon of the instant claims given the disclosure of WO'101. The instant claim would have been obvious to one of ordinary skill in the art at the time of invention given the disclosure of WO'101.

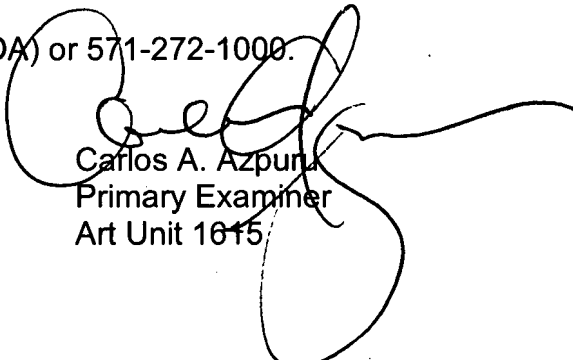
Claim 187 is objected to as dependent upon a rejected base claim.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Carlos A. Azpuru
Primary Examiner
Art Unit 1615

caz